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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

US BIOSERVICES CORP.,

Defendant.

17 Civ. 6353 (CM)

STIPULATION AND ORDER OF
SETTLEMENT AND DISMISSAL

WHEREAS, this Stipulation and Order of Settlement and Dismissal (the "Stipulation") is entered into by and between plaintiff the United States (the "United States" or the "Government"), by its attorney Joon H. Kim, Acting United States Attorney for the Southern District of New York; and defendant US Bioservices Corp. ("US Bio," and together with the Government, the "Settling Parties"), through their respective authorized representatives;

WHEREAS, on August 22, 2017, the United States filed the above-captioned action (the "Action") in the United States District Court for the Southern District of New York (the "Court") pursuant to the False Claims Act (the "FCA"), 31 U.S.C. § 3729 *et seq.*, alleging, *inter alia*, that defendant US Bio violated the FCA and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), in connection with distributing the iron chelation drug Exjade through the Exjade Patient Assistance and Support Services ("EPASS") network;

Whereas, the Government alleges that, from in or about August 2010 to in or about March 2012, US Bio violated the FCA and AKS by participating in an arrangement with Novartis Pharmaceutical Corporation ("Novartis") under which US Bio could receive additional patient referrals and related benefits in return for achieving a higher refill percentage for Exjade patients as compared to the refill percentages among Exjade patients at the other EPASS pharmacies (the "Covered Conduct");

WHEREAS, the United States and US Bio have reached a full and final mutually agreeable resolution of these claims;

NOW, THEREFORE, IT IS HEREBY ORDERED that:

1. US Bio agrees that this Court has subject matter jurisdiction over this action and consents to this Court's exercise of personal jurisdiction over US Bio.
2. US Bio admits, acknowledges, and accepts responsibility for the following facts:
 - a. In December 2005, US Bio signed a contract with Novartis relating to the distribution of Exjade. Under that contract, Novartis agreed that US Bio would be one of three specialty pharmacies (the "EPASS pharmacies") permitted to dispense Exjade as part of Novartis's EPASS network. US Bio, in turn, agreed to provide specialty pharmacy services to Exjade patients, including having clinical staff available to speak with patients and to answer clinical questions or concerns about Exjade.
 - b. To prescribe Exjade through EPASS, physicians wrote prescriptions on EPASS enrollment forms and submitted those forms to EPASS. Patient prescriptions submitted to EPASS were then distributed among the three EPASS pharmacies.
 - c. Within EPASS, some patient prescriptions were designated to a particular pharmacy based on insurance requirements or physician/patient preference. The distribution of the remaining patient prescriptions (the "undesignated patient referrals") among the three EPASS pharmacies was made at the direction of Novartis.
 - d. Exjade patient referrals had economic value to US Bio because having more patients resulted in higher sales revenue, more dispensing fees, and additional rebates.
 - e. Nearly all of the Exjade that US Bio dispensed to patients was shipped by mail. After a physician prescribed Exjade to a patient, and upon receiving the patient referral from EPASS, US Bio called the patient and, if the patient or

caregiver agreed to the initial order, dispensed the initial Exjade shipment. For prescribed refills, US Bio also called patients and, if the patients agreed to order refills, dispensed additional Exjade shipments. Even if a physician had prescribed such a refill, US Bio required patient consent before it could ship a refill to an Exjade patient.

- f. Pursuant to its contract with Novartis, US Bio collected data on the reasons that Exjade patients stopped ordering refills and provided such data to EPASS. That data showed that side effects and physicians' orders to discontinue therapy were among the common reasons for Exjade patients to stop ordering refills.
- g. In or about June 2007, Novartis began issuing monthly "Exjade Scorecards" to US Bio and the other two EPASS pharmacies that measured, among other things, the pharmacies' "adherence" scores. The "adherence" score in the Exjade Scorecards showed how long Exjade patients continued to order refills, without excluding patients who stopped ordering refills due to side effects or patients who were directed to stop therapy by their physicians. Starting in or about July 2007, Novartis had discussions with US Bio regarding how US Bio could improve its "adherence" scores in the Exjade Scorecards.
- h. In late 2007 and early 2008, and to improve its "adherence" score, US Bio trained its nurses to call Exjade patients and tell patients that not treating iron overload, for which Exjade is prescribed, could have severe consequences like organ failure, and that while Exjade had certain common side effects like diarrhea, such side effects typically went away with time. The nurses at US Bio did not use written scripts for the calls with Exjade patients.
- i. In addition to having nurses call Exjade patients, US Bio also assigned a group of patient care coordinators ("PCCs") to call Exjade patients to remind them about refill orders and about their initial Exjade shipments. US Bio assigned budgeted goals to the PCCs in terms of the number of Exjade refill orders they should aim to obtain.

- j. In October 2008, Novartis implemented a new plan for allocating Exjade patient referrals among US Bio and the other EPASS pharmacies. Under that plan, Novartis would allocate 60% of all undesignated patient referrals to the EPASS pharmacy with the top “adherence” scores in the Exjade Scorecards and allocate 20% of the undesignated patient referrals to each of the other two EPASS pharmacies.
- k. Between 2008 and 2012, Novartis and US Bio amended their EPASS contract several times. None of the amended agreements described the basis for determining the undesignated patient referrals US Bio would receive.
- l. In late March 2012, Novartis notified US Bio that, starting in April 2012, it would stop allocating additional Exjade patient referrals to the EPASS pharmacy with the highest Exjade Scorecard ranking. Between 2008 and March 2012, US Bio did not receive 60% of the undesignated patient referrals.
- m. The EPASS contract between US Bio and Novartis expired on March 31, 2012, and US Bio and Novartis did not renew that contract.

3. In settlement of the United States’ claims against US Bio in this action, US Bio shall pay to the United States the sum of ten million and six hundred forty-two thousand and thirteen dollars (\$10,642,013) (the “Settlement Amount”), plus interest, compounded annually at the rate of 2%, accruing from June 21, 2017, to the date of payment. US Bio shall pay the Settlement Amount within fifteen (15) days of the Effective Date of this Stipulation (as defined in Paragraph 20 below).

4. Subject to the exceptions in Paragraph 5 below (concerning excluded claims), conditioned upon US Bio’s timely payment of the Settlement Amount pursuant to Paragraph 3, and subject to Paragraph 12 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date or any payment made pursuant to this Stipulation), the United States, on behalf of itself, its agencies, departments and officers, releases US Bio, as well as US Bio’s current and former parent corporations; direct and indirect subsidiaries, brother or sister

corporations, divisions, current or former corporate owners, and the corporate successors and assignees from any civil or administrative monetary claim that the United States has for the Covered Conduct under the False Claims Act, Civil Monetary Penalties Laws (42 U.S.C. § 1320a-7a), and Program Fraud Civil Remedies Act (31 U.S.C. §§ 3801-3812), as well as the common law theories of fraud, unjust enrichment and payment by mistake.

5. Notwithstanding the release given in Paragraph 4 of this Stipulation, or any other term of this Stipulation, the following claims of the United States are specifically reserved and are not released by this Stipulation:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as expressly stated in this Stipulation, any administrative liability, including mandatory and permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based on obligations created by this Stipulation; and
- f. Any liability of individuals.

6. US Bio waives and shall not assert any defenses it may have to any federal criminal prosecution or federal administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Stipulation bars a remedy sought in such federal criminal prosecution or federal administrative action. Nothing in this paragraph or any other provision of this Stipulation constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

7. US Bio, together with its parent corporations and direct and indirect subsidiaries, fully and finally releases the United States, and its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that US Bio has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

8. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment for any reason related to the Covered Conduct by any Medicare carrier or intermediary, or any federal or state payer; and US Bio agrees not to resubmit to any Medicare carrier or intermediary or any federal or state payer any claims previously denied for any reason related to the Covered Conduct, and agrees not to appeal any such denials of claims.

9. US Bio shall be in default of this Stipulation if it fails to pay the Settlement Amount as set forth in Paragraph 3 on or before the due date for such payment. The United States will provide written notice of any default, to be sent by e-mail and first-class mail to one or more of the counsel for US Bio identified in Paragraph 19. In the event of default, the entire remaining unpaid balance of the Settlement Amount shall be immediately due and payable by US Bio, and interest shall accrue at the rate of 12% per annum compounded daily on the remaining unpaid principal balance, beginning seven (7) business days after delivery of the notice of default. If the Settlement Amount, with all accrued interest, is not paid in full within seven (7) business days following delivery of the notice of default, US Bio agrees to the entry of a consent judgment in the form attached hereto as Exhibit A and that the United States may take action to collect on the consent judgment. US Bio further agrees that the United States also may, at its option, (a) rescind this Stipulation and assert claims against US Bio for the Covered Conduct; (b) seek

specific performance of the Stipulation; (c) offset the remaining unpaid balance from any amounts due and owing US Bio at the time of default by any department, agency, or agent of the United States; or (d) exercise any other rights granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. US Bio shall not contest any offset imposed or any collection action undertaken by the United States pursuant to this paragraph, either administratively or in any federal or state court. In addition, US Bio shall pay the United States all reasonable costs of collection and enforcement under this paragraph, including attorneys' fees and expenses. In the event that the United States opts to rescind this Stipulation, US Bio shall not plead, argue, or otherwise raise any defense under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that relate to the Covered Conduct.

10. US Bio agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of US Bio, its present or former officers, employees, and agents in connection with:

- (1) the matters covered by this Stipulation;
- (2) the United States's civil investigation of the Covered Conduct;
- (3) the investigation, defense, and corrective actions undertaken by US Bio in response to the United States's civil investigation of the Covered Conduct (including attorney's fees);
- (4) the negotiation and performance of this Stipulation;
- (5) the payments US Bio makes to the United States pursuant to this Stipulation; and

- (6) the negotiation of, and obligations undertaken pursuant to any integrity agreement relating to the Covered Conduct with HHS-OIG to (i) retain an independent review organization to perform annual reviews required by any such integrity agreement, and (ii) prepare and submit reports to the HHS-OIG,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in this Paragraph, *i.e.*, Paragraph 15(a), that may apply to the obligations undertaken pursuant to any such integrity agreement affects the status of costs that are not allowable based on any other authority applicable to US Bio.

- b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by US Bio, and US Bio shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by US Bio or any of its agencies or departments to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: US Bio further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by US Bio or any of its agencies or departments, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. US Bio agrees that the United States, at a minimum,

shall be entitled to recoup from US Bio any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. The United States reserves its rights to disagree with any calculations submitted by US Bio or any of its rights to audit, examine, or re-examine US Bio's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph, and to disagree with any calculations submitted by US Bio or any of its agencies or departments concerning any Unallowable Costs included in payments previously sought by US Bio, or the effect of any such Unallowable Costs on the amount of such payments.

11. US Bio represents and warrants that it has reviewed its financial condition, that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and that it reasonably believes that it shall remain solvent following payment to the United States of the Settlement Amount. Further, the Settling Parties warrant that, in evaluating whether to execute this Stipulation, they (a) have intended the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to US Bio, within the meaning of 11 U.S.C. § 547(c)(1), and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Settling Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which US Bio was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

12. If within 91 days of the Effective Date of this Stipulation or of any payment made under this Stipulation, US Bio commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors

(a) seeking to have any order for relief of US Bio's debts, or seeking to adjudicate US Bio as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for US Bio or for all or any substantial part of US Bio's assets, US Bio agrees as follows:

- a. US Bio's obligations under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and US Bio shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) US Bio's obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) US Bio was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Stipulation do not constitute a contemporaneous exchange for new value given to US Bio.
- b. If US Bio's obligations under this Stipulation are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against US Bio for the claims that would otherwise be covered by the releases provided in Paragraph 4. US Bio agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceedings described in the first clause of this Paragraph, and US Bio shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) US Bio shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the United States within 60 calendar days of written notification to US Bio that the releases have been rescinded pursuant to this Paragraph; and (iii) the United States has a valid claim against US Bio in the Settlement Amount, and the United States may pursue its claim in the case, action, or proceeding

referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

- c. US Bio acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Stipulation.

13. US Bio agrees that it waives and shall not seek payment of any of the health care billings covered by this Stipulation from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims submitted in connection with the Covered Conduct.

14. Except as expressly provided to the contrary in this Stipulation, this Stipulation is intended to be for the benefit of the Settling Parties only. The Settling Parties do not release any claims against any other person or entity.

15. This Stipulation is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Stipulation is the United States District Court for the Southern District of New York. For purposes of construing this Stipulation, it shall be deemed to have been drafted by both Settling Parties, and shall not, therefore, be construed against either Settling Party for that reason in any subsequent dispute.

16. Each of the Settling Parties shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation.

17. The undersigned counsel and other signatories represent and warrant that they are fully authorized to execute this Stipulation on behalf of the persons and entities indicated below.

18. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

19. Any notice pursuant to this Stipulation shall be in writing and shall, unless

expressly provided otherwise herein, be delivered by express courier and by e-mail transmission, followed by postage-prepaid mail, to the following representatives:

TO THE UNITED STATES:

Li Yu
Mónica P. Folch
Assistant United States Attorneys
Southern District of New York
86 Chambers Street, 3rd Floor
New York, NY 10007
E-mail: Li.Yu@usdoj.gov
Monica.Folch@usdoj.gov

TO US BIO:

Eric W. Sitarchuk, Esq.
Meredith S. Auten, Esq.
Maire E. Donovan, Esq.
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103-2921
Email: Eric.Sitarchuk@morganlewis.com
Meredith.Auten@morganlewis.com
Maire.Donovan@morganlewis.com

20. The effective date of this Stipulation is the date upon which this Stipulation is entered by the Court (the "Effective Date").

21. Subject to the exceptions set forth in Paragraphs 5, 9, and 12, and conditioned upon the payment of the Settlement Amount in full by US Bio, the United States shall dismiss its Complaint in this action with prejudice.

22. This Stipulation constitutes the complete agreement between the Settling Parties.
This Stipulation may not be amended except by written consent of the Settling Parties.

For the United States:

Dated: August 22, 2017

JOON H. KIM
Acting United States Attorney

By: 

LI YU
MÓNICA P. FOLCH
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007

For US Bio:

Dated: August 21, 2017

MORGAN, LEWIS & BOCKIUS LLP

By: 

ERIC W. SITARCHUK, Esq.
MEREDITH S. AUTEN, Esq.
MAIRE E. DONOVAN, Esq.
1701 Market Street
Philadelphia, PA 19103

SO ORDERED:


COLLEEN McMAHON
CHIEF UNITED STATES DISTRICT JUDGE

8-22-2017

Exhibit A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----	X	
UNITED STATES OF AMERICA,	:	17 Civ. ----
	:	
Plaintiff,	:	<u>CONSENT JUDGMENT</u>
v.	:	
	:	
US BIOSERVICES CORP.,	:	
	:	
Defendant.	:	
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Upon the consent of plaintiff the United States of America (the "Government") and defendant US Bioservices Corp. ("US Bio"), following entry of a Stipulation and Order of Settlement and Dismissal;

It is hereby **ORDERED, ADJUDGED AND DECREED**: that the Government is awarded judgment in the sum of \$10,642,013, plus all applicable interest accruing from June 21, 2017, as against US Bio.

Consented to:

For the Government:

Dated: August 2_, 2017

JOON H. KIM
Acting United States Attorney

By: _____
LI YU
MÓNICA P. FOLCH
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007

For US Bio:

Dated: August 2_, 2017

MORGAN, LEWIS & BOCKIUS LLP

By: _____
ERIC W. SITARCHUK, Esq.
MEREDITH S. AUTEN, Esq.
MAIRE E. DONOVAN, Esq.
1701 Market Street
Philadelphia, PA 19103

SO ORDERED:

COLLEEN McMAHON
CHIEF UNITED STATES DISTRICT JUDGE